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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,704	08/15/2000	CATHARINA SVANBORG	032313-004	3220

21839 7590 05/22/2003

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/22/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/554,704

Applicant(s)

SVANBORG ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/9/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-22, 24, 25 and 28-46 is/are rejected.
- 7) ☐ Claim(s) 23, 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The sequence amendment filed on May 9, 2003 has been received and entered.

Abstract

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim objections

3. Claims 23, 26, 27 are objected to as depending from a rejected based claim.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-46 are rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claims 1, 2 and the dependent claims hereto are indefinite because the claim recites, "at least some of which is in the molten globule-like state" and it is unclear as to how much of the protein is going to be in this state. What quantity corresponds to "at least some" (see also claim 42)?

Claim 6 is indefinite because the claim recites "substantial portion" and it is unclear as to how much is "substantial". It is noted that page 4 of the specification discloses an example of greater than 50% w/w, however, this disclosure is exemplary, not limiting. The claims are also indefinite as to "conversion reagent" as none is defined.

Claims 10 and 11 are indefinite for the recitation of "low pH" as it is unclear what pH is considered to be "low".

Claim 12 is indefinite with respect to 25-120 degrees Celsius (see for example, the notation in claim 13).

Claims 14 and 15 lack antecedent basis as the claim recites "a reagent" and the claims from which it depends recite "a conversion reagent".

Claim 16 is indefinite for the recitation of the acronym EDTA, as the spelled out meaning of the acronym is not recited in the claim (see also claim 36 with respect to "DEAE").

Claims 17-19 lack antecedent basis as claim 17 recites a method according to any one of claims 1 to 16 and claims 14 and 15 recite "reagent/inducing reagent", not "conversion reagent".

Claim 20 is indefinite because the requires a "mutated form" of the native form of alpha-lactalbumin wherein the calcium binding sites are modified, however, there is no indication as to how they are modified.

Claim 21 is indefinite because the claim recites, "at least some of cysteine residues of the alpha-lactalbumin are mutated" and it is unclear as to what quantity equates with "at least some" or what the mutation is.

Claim 24 is indefinite for the recitation of "substantially pure form" because it is unclear how pure is "substantial" and the specification provides no definition.

Claims 28-32, 35, 37, 38, 39, 40, 43 and 46 are indefinite because the claim depends from a rejected based claim.

Claim 33 is indefinite because the claim is missing the transitional phrase "a" where it recites, "alpha-lactalbumin is subjected to pre-treatment step involving exposure to a low pH". The claim is also indefinite as to the recitation of "low pH", what is considered "low".

Claim 34 is indefinite as to "heated to an elevated temperature", what temperature is required for this method step?

Claims 41 and 42 are indefinite as the claims depend from "any one of the preceding claims" and "any one of claims 1 to 40" and the claims lack antecedent basis for the recitation of "said source of alpha-lactalbumin" and not all of the preceding claims or claims 1-40 recite "source of alpha-lactalbumin".

Claim 45 appears to be missing a transitional phrase where the claim recites "an ion exchange column which comprises ion exchange medium".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 6 and 28 are rejected under 35 U.S.C. 102(b) as been anticipated by Jegouic et al. (Journal of Agricultural and Food Chemistry, vol. 45, no. 1, pages 19-22, January 1997).

Jegouic et al. teach baric oligomerization of alpha-lactalbumin that is treated with low-molecular weight reducing thiols (conversion reagents) see page 19, lines 1-5 of the introduction. This treatment partially unfolds the proteins and converts them into a molten globule-like state (reduction of the disulfide bonds, page 5 of the specification), see claim 1 of the instant application. The reference teaches that the contact between alpha-lactalbumin and the conversion agent (reducing thiols) is achieved under conditions which would allow ion exchange to take place (claim 2) see pages 19-20 of the reference. As the specification does not clearly define what is considered to be a "substantial portion" with respect to the amount of the protein that is in the molten

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globule-like state, claims 6 and 28 are anticipated by the reference. Thus, the limitations of the claims are met by this reference.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103 (a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

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7. Claims 1, 2, 3, 6, 14, 17, 18, 22, 25, 28, 35, 36, 37, 38, 39, 40, 41, 42 and 46 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jegouic et al. (Journal of Agricultural and Food Chemistry, vol. 45, no. 1, pages 19-22, January 1997) in view of Sabharwal (WO 96/04929, February 22, 1996 and Ohgushi et al. (FEBS Letters, vol. 164, no. 1, pages 21-25, 1983).

Jegouic et al. teach baric oligomerization of alpha-lactalbumin that is treated with low-molecular weight reducing thiols (conversion reagents) see page 19, lines 1-5 of the introduction. This treatment partially unfolds the proteins and converts them into a molten globule-like state (reduction of the disulfide bonds, page 5 of the specification), see claim 1 of the instant application. The reference teaches that the contact between alpha-lactalbumin and the conversion agent (reducing thiols) is achieved under conditions which would allow ion exchange to take place (claim 2) see pages 19-20 of the reference. As the specification does not clearly define what is considered to be a "substantial portion" with respect to the amount of the protein that is in the molten globule-like state, this claim is rendered obvious by the reference. Jegouic et al. teach an alpha-lactalbumin separated from cow's milk (claim 41, page 19). In-so-far-as Jegouic et al. do not teach human alpha lactalbumin, Sabharwal teaches alpha lactalbumin separated from the milk of lactating women purified by fractionation of casein by ion exchange chromatography and eluting after 1M NaCl (claims 2, 3, 42, 14, 17, 18, 22, 25, 35, 37, 39, 40, and 46, pages 1-5). Sabharwal teaches the use of the ion exchange column medium with DEAE-Tris-acryl and the buffer Tris-HCL (claims 36 and 38, page 5).

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Therefore, it would have been obvious to one of skill in the art to arrive at the claimed invention as a whole because Jegouic et al. teach a method to produce an oligomeric form of alpha-lactalbumin that is contacted with a conversion reagent (thiols) resulting in a molten globule-like state from cow's milk and Sabharwal teach alpha-lactalbumin source on an ion exchange medium comprising casein from human milk. One of skill in the art would be motivated to combine the teachings of the references because Ohgushi et al. teach that alpha-lactalbumin may indicate that the molten-globule state is a general trend which occurs in globular protein molecules (page 23). Moreover, Ohgushi et al. teach that the molten-globule state will provide a suitable transit for fast folding of a polypeptide chain into a unique structure and that this state with side chains having high internal freedom of motion can play an important role in efficient enzyme action or in other biochemical functions in globular proteins (page 24). Thus, the claimed invention as a whole was within the skill of the art.

Conclusion

8. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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